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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,563	04/16/2004	Mark A. Hoffman	CRNI.114071	2108

46169 7590 07/24/2008

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,563	HOFFMAN ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-8,10,12-15,17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-8,10,12-15,17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/2008 and 4/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/9/2008 has been entered.

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, filed 4/9/2008, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments. Therefore, the rejection has been withdrawn.

The following is a newly applied rejection:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 are drawn to a process and/or system and/or computer software product or computer readable medium. A statutory process or a system or a computer program product that embodies a statutory process must

include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). Furthermore, a system w/out any physical limitations, which recites only "instructions" type of limitations encompasses a program, per se. A program, per se, is not statutory subject matter. The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

> The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to

be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 do not produce a tangible result. A tangible result requires that the claims must set forth a practical application to produce a real-world result. In the instant claims such as claim 1, the preamble and final method step comprises a generation of output including information regarding the likelihood a person has a gene variant indicative of an atypical event. It is unclear as to what is done with the resulting data of the final method step. For instance, the resulting data may be seed data for another data manipulation program, wherein the instant scenario the result is clearly not tangible. Furthermore, claim 15 recites in the preamble a computer readable medium, which is appreciated as it attempts to cause said claim to be drawn to statutory subject matter. However, the specification defines computer readable medium broadly, which include "computer storage media and communication media," wherein "communication media typically embodies computer readable instructions, data structures, program modules, or other data in a modulated data signal, such as a carrier wave." Therefore, the wording "computer readable medium" is being reads on carrier waves, which cause said claims to being drawn to non-statutory subject matter. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or to a user, or by including a final

resulting step of a physical transformation, if such wording is supported by the instant specification.

The following is a newly applied rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) (This reference has been submitted via IDS filed on 4/11/2008 and therefore will not be cited on a separate 892 form) in view REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000).

The claims are drawn to a computer system, computer readable medium and a method in a computer system for generating an output including information regarding the likelihood a person has a gene variant indicative of an atypical event, comprising the steps of:

a) receiving clinical agent information, the clinical agent information including an identifier of the agent;

b) accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information;

c) inquiring if the person has a stored genetic test result value for the gene variant;

d) accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant;

e) utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; and

f) generating an output including information regarding the likelihood a person has a gene variant indicative of an atypical event based on hereditary information.

ICHIKAWA teaches at page 523, first column, 2nd and 3rd paragraphs data related to azathioprine or mercaptopurine (clinical agents), which reads on step a) receiving clinical agent information, the clinical agent information including an identifier of the agent. ICHIKAWA at page 523, 3rd and 4th paragraphs, teaches about thiopurine S-methyl transferase (TPMT), which has genetic polymorphisms associated with one or more atypical events for the clinical agents, which reads on step b) accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the clinical agent information. ICHIKAWA at page 523, first column, last 5 lines, teaches it is quite important to know in advance whether a patient who will be treated with thiopurine derivitives, has genetic polymorphism at TPMT sites, which reads on step c) inquiring if the person has a stored genetic test result value for the gene variant. ICHIKAWA at page 523, second column, first paragraph teaches a method for processing hereditary (genetic) information related to response to

azathioprine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are accessed, which reads on step d) accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant. ICHIKAWA further teaches at page 523, first column, last paragraph and second column first paragraph that the presence of a polymorphism is then determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage, which reads on step e) utilizing the hereditary information for the person to determine the likelihood the person has the gene variant. Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results, which reads on step f) generating an output including information regarding the likelihood a person has a gene variant indicative of an atypical event based on hereditary information.

ICHIKAWA does not explicitly teach the computer aspect of accessing a data structure in step b), or the computer implemented aspects of the instant steps.

Rienhoff et al. at the abstract, teach a computer program product that allows identification of a susceptibility locus in individuals using genetic screening methods to assess their risk of certain diseases wherein the information can be used to gauge drug responses.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the computer implemented methods for allowing identification of a susceptibility locus in individuals using genetic screening methods to

assess their risk of certain diseases wherein the information can be used to gauge drug responses as taught by Rienhoff et al. to identify individuals with genetic polymorphisms of TPMT sites prior to the administration of the clinical agents. This is because ICHIKAWA at page 524, states that it would be possible to anticipate the effectiveness and side effects of all drugs, not after the administration of the drugs, but in advance based on the information of genetic polymorphism. Furthermore, the automation of such a method as taught by Rienhoff et al. would have been obvious because it would increase efficiency of testing and data management. Therefore, to use the computer program product taught by Rienhoff et al. to automate the method taught by ICHIKAWA, one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved method.

ICHIKAWA also teaches at page 523, second column, paragraphs 1 and 2, wherein the hereditary information includes ethnicities as in claims 3, 10, and 17.

Rienhoff et al. at paragraphs [0006]-[0007] teach the use of comprehensive medical databases for storing hereditary information. Furthermore, Rienhoff et al. at paragraph [0011]-[0012] teach determining, storing, and comparing polymorphic genomic profiles of individuals in databases wherein these databases are used to assist in performing clinical trials and drug administration (see paragraph [0014]), which reads on a broad interpretation of a comprehensive healthcare system as in claims 5, 12, and 19.

Reinhoff et al. at paragraph [0010] teach a computer program that allows identification of a susceptibility locus in individuals using genetic screening methods to

assess individuals' risk of certain diseases. Reinhoff et al. at paragraph [0011] teach determining a statistically significant difference between the polymorphic profiles for each individual of the population and separating the population into a first subpopulation and a second subpopulation based up the profiles. Reinhoff et al. teach at paragraph [0014] wherein databases may be updated and expanded. Moreover, Reinhoff et al. at paragraph [0027] teach how an individual's polymorphic profile can be ordered and stored, which reads on claims 6,7, 13, 14, 20, and 21.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631